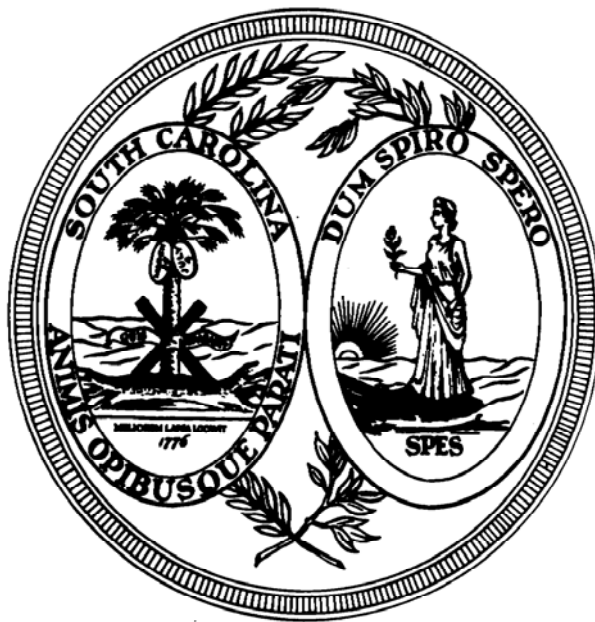




## **Regulation Number 61-106 Tanning Facilities**



**Promulgated by the Board of Health and Environmental Control**

**Administered by the Division of Health Licensing**

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## **Tanning Facilities**

### **61-106. Tanning Facilities**

#### **PART I**

#### **GENERAL PROVISIONS**

##### **1.1 Scope**

1.1.1 These regulations provide for the registration and regulation of facilities, equipment and persons installing and/or servicing equipment which employs ultraviolet and other lamps for the purpose of tanning the skin of the human body through the application of ultraviolet radiation.

1.2.2 Nothing in these regulations shall be interpreted as limiting the intentional exposure of patients to ultraviolet radiation for the purpose of medical treatment or therapy prescribed and supervised by a physician who is licensed by the South Carolina Board of Medical Examiners.

##### **1.2 Definitions:**

As used in this regulation:

1.2.1 “Act” means Atomic Energy and Radiation Control Act, Section 13-7-10 et seq, 1976 Code of Laws of South Carolina.

1.2.2 “Consumer” means any individual who is provided access to a tanning facility which is required to be registered pursuant to provisions of this regulation.

1.2.3 “Department” means the South Carolina Department of Health and Environmental Control.

1.2.4 “Formal Training” means a course of instruction reviewed and approved by the Department which is conducted or presented under formal classroom conditions by a person or persons possessing adequate knowledge and experience to offer a curriculum, associated training and certification testing pertaining to and associated with the correct use of tanning equipment.

1.2.5 “Individual” means any human being.

1.2.6 “Inspection” means an official examination or observation including but not limited to tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the Department.

1.2.7 “Minor” means any individual less than eighteen (18) years of age.

1.2.8 “Operator” means any individual designated by the registrant to operate or to assist and instruct the consumer in the operation and use of the tanning facility or tanning equipment. Under this definition, the term “operator” means any individual who conducts one or more of the following activities:

- 1) determining consumers’ skin type;
- 2) determining the suitability for use of a tanning device by prospective consumers;

- 3) informing the consumer of the dangers of ultraviolet radiation exposure including photoallergic reactions and photosensitizing reactions;
- 4) determining consumer use of potentially photosensitizing agents;
- 5) assuring the consumer reads and properly signs all forms required by these regulations;
- 6) reviewing, signing, and ensuring required documentation is completed for minors or illiterate or visually impaired consumers;
- 7) maintaining required consumer exposure records;
- 8) recognizing and reporting consumer actual or alleged ultraviolet radiation injuries to the registrant;
- 9) determining the consumers' exposure schedule, to include exposure time, spacing of visits, number of allowed visits per week and maximum exposure time in minutes, in accordance with the applicable manufacturers' recommended exposure schedule or Department approved alternate exposure schedule;
- 10) instructing the consumer in the proper use of protective eyewear; and
- 11) setting timers which control the duration of exposure.

1.2.9 "Override Timer Control" means a separate electrical timer, switch, or similar device which may be used by the operator to start or stop the timer system for a tanning device. The term does not include electric panels which control the entire electrical system for a building or a portion of a building.

1.2.10 "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of these entities.

1.2.11 "Personal Use" means tanning equipment that is used solely by an individual and the individual's immediate family or permanent residents of the individual's place of residence. Immediate family is defined as the spouse, great-grandparents, grandparents, parents, brothers, sisters, children, grandchildren, great-grandchildren of either the owner of the tanning equipment or the spouse.

1.2.12 "Registrant" means any person who is registered with the Department as required by provisions of this regulation.

1.2.13 "Registration" means registering with the Department in accordance with provisions of this regulation.

1.2.14 "Sanitize" means the effective fungal, viral and bacterial treatment of surfaces of tanning equipment by an EPA and DHEC approved product which provides a sufficient concentration of chemicals and enough time to reduce the bacterial count, including pathogens, to an acceptable level.

1.2.15 "Tanning Components" means any constituent tanning equipment part, to include ballasts, starters, lamps, reflectors, acrylic shields, timers, and airflow cooling systems.

1.2.16 “Tanning Equipment” means ultraviolet or other lamps and equipment containing such lamps intended to induce skin tanning through the irradiation of any part of the living human body with ultraviolet radiation.

1.2.17 “Tanning Facility” means any location, place, area, structure or business which provides consumers access to tanning equipment. For the purpose of this definition tanning equipment registered to different persons at the same location and tanning equipment registered to the same person, but at separate locations, shall constitute separate tanning facilities.

1.2.18 “Ultraviolet Radiation” means electromagnetic radiation with wavelengths in air between two hundred nanometers and four hundred nanometers.

1.2.19 “Unlimited” means any number of visits implied or allowed in excess of the number of visits per week allowed by the tanning equipment manufacturer’s recommended exposure schedule or the Department approved alternate exposure schedule.

1.2.20 “Vendor” means any person or persons providing tanning equipment installation, servicing, and/or services. This shall include, but not be limited to: any person or persons who make, sell, lease, transfer, lend, assemble, repair or install tanning equipment or the components used in connection with such equipment; any person or persons who performs health physics consulting, such as calibration of equipment used to perform surveys of ultraviolet radiation and timer accuracy measurements, performs ultraviolet radiation output and timer accuracy measurements, designs ultraviolet radiation safety programs or procedures; any person or persons who perform preventive maintenance or cleaning services, such as the cleaning of fans, acrylic, lamps, reflectors and other components; any person or persons who conduct training seminars for tanning equipment operators and service personnel.

### **1.3 Compliance with Other Laws:**

The registrant shall comply with any other applicable federal, state and local regulations dealing with health, sanitation, safety standards and electrical standards.

### **1.4 Inspections:**

1.4.1 Each registrant shall afford, at all reasonable times, the Department or its duly authorized representative the opportunity to inspect equipment and the premises wherein such tanning equipment is used or stored.

1.4.2 Each registrant shall make available to the Department or its authorized representative for inspection, upon one day’s notice, records maintained pursuant to this regulation.

### **1.5 Exemptions:**

1.5.1 The Department may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of this regulation as it determines are authorized by law and will not result in undue hazard to public health and safety.

1.5.2 Any person is exempt from the provisions of this regulation to the extent that such person uses equipment other than tanning equipment which emits ultraviolet radiation incidental to its normal operation.

1.5.3 Any individual is exempt from the provisions of this regulation to the extent that such individual owns tanning equipment exclusively for personal use.

1.5.4 Tanning equipment while in transit or storage incidental thereto is exempt from the provisions of this regulation.

## **1.6 Additional Requirements:**

The Department may, by order, impose upon any registrant such requirements in addition to those established in this regulation as it deems appropriate or necessary to minimize danger to public health and safety or property.

## **1.7 Violations:**

1.7.1 Any person found in violation of this regulation shall notify the Department in writing within twenty calendar days from the date of citation with respect to action that has been taken or planned to correct the violation.

1.7.2 All violations shall be corrected within sixty (60) calendar days from the date of citation. The respondent shall notify the Department in writing of all action taken to correct all violations.

1.7.3 The Department is authorized to hold public hearings, compel attendance of witnesses, make findings of fact and determinations and to assess fines and civil penalties relating to violations of the provisions of the Act or any regulation, temporary or permanent order, or final determination of the Department.

1.7.4 The Department may impose a civil penalty not to exceed Twenty-five Thousand Dollars (\$25,000.00) on a person who violates a provision of the Act, rules, regulations, or orders issued. Each day of continued violation shall constitute a separate offense in computing the civil penalty. Civil penalties shall be assessed as specified in Section 1.13.

## **1.8 Enforcement:**

1.8.1 Upon determination by the Department that the Act or these regulations have been violated or that a public health risk exists, the Department will:

1.8.1.1 Provide written notification to the noncompliant facility as soon as possible after violations are noted which:

1.8.1.1.1 Cites each section of the Act or regulations violated.

1.8.1.1.2 Specifies the manner in which the registrant failed to comply.

1.8.1.1.3 Requires submission of a timely and comprehensive corrective action plan, including a time schedule for completion of the plan.

1.8.1.1.4 Stipulates a firm time schedule within which a corrective action plan needs to be submitted; the Department will approve the plan and the proposed time schedule for its completion if the plan is adequate.

1.8.1.2 In cases where the registrant fails to comply with the conditions of the written notification sent, a certified letter will be sent ordering compliance and advising appropriate persons that unless corrective action is initiated within ten days, the Department will seek further enforcement action, appropriate penalties and/or direct remedial relief.

1.8.1.3 If the registrant fails to comply with the requirements of the certified letter within ten days, the Department will take one or a combination of the following steps:

1.8.1.3.1 Issue an administrative order which:

1.8.1.3.1.1 Imposes an appropriate civil penalty; or

1.8.1.3.1.2 Requires corrective action; or

1.8.1.3.1.3 Revokes the facility's registration in accordance with Section 2.8; or

1.8.1.3.1.4 Impounds or orders the impounding of sources of ultraviolet radiation in accordance with the Act;

1.8.1.3.2 Request the Department attorney or the attorney general to seek court action to enjoin violations and seek conviction for a simple misdemeanor; or

1.8.1.3.3 Take other enforcement action that the Department feels appropriate and necessary and is authorized by law.

1.8.2 Under an actual or potential condition posing a risk to any individual comparable to a Major severity level violation, the Department may immediately impound or order the impounding of sources of ultraviolet radiation in accordance with the Act.

## **1.9 Impounding:**

The Department may immediately impound or order the impounding of tanning equipment in the possession of any person who fails to observe these regulations or provisions of the Act, or when the Department deems a situation to constitute an emergency.

## **1.10 Records:**

Each registrant shall keep records showing the receipt, transfer, repair and disposal of all tanning equipment and components. These records shall be maintained by the registrant for no less than two years and shall be readily available at the tanning facility for Department review. Additional record requirements are specified elsewhere in these regulations.

## **1.11 Fees:**

1.11.1 Application Fee:

Each registrant shall pay a nonrefundable initial application fee of fifty dollars upon submission of the "Application for Registration of Tanning Facilities" form.

1.11.2 Tanning Equipment Fee:

1.11.2.1 Each registrant shall pay fifty dollars for each piece of tanning equipment.

1.11.2.2 The tanning equipment fee shall be due upon initial registration approval and on July 15 of each year.

1.11.3 Tanning Equipment Vendor Fee:

1.11.3.1 Each registrant providing tanning equipment installation, servicing and/or services shall pay an annual registration fee of one hundred dollars.

1.11.3.2 The registration fee shall be due upon initial application and on July 15 of each year.

1.11.4 Persons failing to pay the fees required by Section 1.11.2 or Section 1.11.3 by September 15 of that year shall also pay a penalty of Fifty Dollars. If the required fees are not paid by October 15 of that year, the registrant shall be notified by certified mail to be sent to his last known address that his registration is revoked, and that any activities permitted under the authority of the registration must cease immediately.

1.11.5 A registrant suspended for failure to pay the required fee under Sections 1.11.2, 1.11.3 or 1.11.8 may be reinstated by the Department upon payment of the required fee, the penalty of Fifty Dollars, and an additional penalty of One Hundred Dollars, if the registrant is otherwise in good standing and presents to the Department a satisfactory explanation for his failure to pay the required fee.

1.11.6 Payment of fees shall be made in accordance with the instructions of a "Statement of Fees Due" issued annually or monthly by the Department.

1.11.7 Fees required by Section 1.11.2 or Section 1.11.3 for tanning equipment or vendor registration which is issued during a calendar year shall be prorated for the remainder of that year based on the date of issuance of the registration.

1.11.8 Persons failing to pay the prorated fees required by Section 1.11.7 within sixty days from the billing date shall also pay a penalty of Fifty Dollars. If the required fees are not paid within ninety days of the billing date, the registrant shall be notified by certified mail to be sent to his last known address that his registration is revoked, and that any activities permitted under the authority of the registration must cease immediately.

## **1.12 Communications:**

All communications and reports concerning these regulations, and registrations filed thereunder, shall be addressed to the Department at:

SC Department of Health and Environmental Control  
Radiological Health Branch  
2600 Bull Street  
Columbia, SC 29201

## **1.13 Civil Penalties:**

1.13.1 Assessment - Assessment of civil penalties shall be based on the following criteria:

1.13.1.1 the seriousness of the violation(s);

- 1.13.1.2 previous compliance history;
- 1.13.1.3 the amount necessary to deter future violations;
- 1.13.1.4 efforts to correct the violation; and
- 1.13.1.5 any other mitigating or enhancing factors.

1.13.2 Severity Levels - The seriousness of violations shall be categorized by one of the following severity levels:

1.13.2.1 Major - Violations that are most significant and have a direct negative impact on occupational and/or public health and safety or which represent a significant deviation from the requirements of this regulation.

1.13.2.2 Moderate - Violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances or which represent a moderate deviation from the requirements of this regulation.

1.13.2.3 Minor - Violations that are of minor safety significance or which represent a minor deviation from the requirements of this regulation.

1.13.2.4 In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

1.13.3 Application - Examples of violations in each severity level are given in the Schedule of Civil Penalties. While examples are given for determining the appropriate severity level for violations, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each is designed to illustrate the significance which the Department of Health and Environmental Control places on a particular type of violation of state requirements. Adjustments to the values listed in the Schedule of Civil Penalties under each severity level may be made for the presence or absence of the following factors:

1.13.3.1 Prompt Identification and Reporting. Reduction of a civil penalty may be given when a registrant identifies the violation and promptly reports the violation to the Department. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to the discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to this factor if the registrant does not take immediate action to correct the problem upon discovery.

1.13.3.2 Corrective Action to Prevent Recurrence. Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the registrant takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive corrective action may result in reducing the proposed civil penalty. On the other hand, the civil penalty may be increased if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of registrant initiative, and comprehensiveness of the corrective action-such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.



1.13.3.3 Compliance History. Reduction of the civil penalty may be given for prior good performance in the general area of concern. In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as previous compliance history in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty.

1.13.3.4 Prior Notice of Similar Events. The civil penalty may be increased for cases where the registrant had prior knowledge of a problem as a result of a registrant audit, or specific industry notification, and had failed to take effective preventative steps.

1.13.3.5 Multiple Occurrences. The civil penalty may be increased where multiple examples of particular violation are identified during the inspection period.

1.13.3.6 The above factors are additive. However, the civil penalty will not exceed Twenty-five Thousand Dollars (\$25,000) for any one violation. Each day of noncompliance shall constitute a separate violation.

1.13.4 The Department shall issue civil penalties according to the following schedule:

#### 1.13.4.1 Penalty Matrix

Deviation from Requirement: Potential for Harm:	Major (11-30)	Moderate (4-10)	Minor (1-3)
Major (11-70)	\$10,000-2,200	\$8,000-1,500	\$7,300-1,200
Moderate (6-10)	\$ 4,000-1,700	\$2,000-1,000	\$1,300-700
Minor (0-5)	\$ 3,500-1,100	\$1,500-400	\$800-100

#### Calculation of Base Penalty:

Each violation is assigned a relative point value as follows: Potential for Harm- 0-70, with 70 being maximum harm; Deviation from the Requirement- 1-30, with 30 being the maximum deviation. Add the two values together, convert to a decimal value (15 to .15, for example), and multiply by the maximum per day per violation per civil penalty (\$10,000). This is the base civil penalty per violation. The base penalty may be increased for repeat violations, multi-day penalties and/or degree of recalcitrance, willfulness, negligence, or indifference.

#### Minimum Increase for Repeat Violations Found on Follow-up Inspections or Reinspections

Second Offense (First Follow-up Inspection or First Reinspection)	15%
Third Offense (Second Follow-up Inspection or Second Reinspection)	30%
Fourth Offense (Third Follow-up Inspection or Third Reinspection)	45%
Fifth and Subsequent Offenses	60%

#### Multi-Day Penalties

Increase penalty 1% to 7% for each day of noncompliance.

#### Degree of Recalcitrance, Willfulness, Negligence, or Indifference

Increase penalty 10% to 50%.

1.13.4.2 The Department reserves the right to impose a civil penalty up to Twenty-five Thousand Dollars on a person who operates a tanning facility in such a manner so as to present an imminent hazard to human health and safety. The Twenty-five Thousand Dollars civil penalty may be levied for the following:

1.13.4.2.1 Three or more failures within three consecutive inspections to utilize a consumer warning system and/or a skin/medical history system (R.61-106 Sections 2.3.4, 4.2).

1.13.4.2.2 Three or more failures within three consecutive inspections of failure to ensure consumers either have compliant protective eyewear or are prohibited from tanning (R.61-106 Sections 3.6.1, 3.6.2);

1.13.4.2.3 Two or more incidents within three consecutive inspections of use of lamps for medical use only (R.61-106 Section 3.8.4);

1.13.4.2.4 Seven or more incidents within three consecutive inspections of allowing the operation of tanning equipment in such a manner so as to cause an injury to a consumer resulting from the same cause (R.61-106 Section 5.3.3);

1.13.4.2.5 Three or more incidents within three consecutive inspections of a required system designed to prevent or mitigate a serious safety event is absent or inoperable due to a deliberate act by a registrant such as: removing a timer (R.61-106 Sections 3.4.3, 3.4.5) or device designed to enable the consumer to terminate manually radiation emission (R.61-106 Section 3.4.6); failure to provide compliant physical protective barriers (R.61-106 Section 3.4.8); or, failure to replace defective filters (R.61-106 Section 3.8.3).

#### 1.13.4.3 Examples of Violations with Potential for Harm

##### Major

Three or more failures within three consecutive inspections to correct violations within sixty days when the violations have major safety significance (R.61-106 Section 1.7.2).

Three or more failures within three consecutive inspections to correct violations involving matters pertaining to failure to follow or establish procedures, rules and regulations that have major safety significance (R.61-106 Section 2.3).

Failure to utilize a consumer warning system and/or a skin/medical history system (R.61-106 Sections 2.3.4, 4.2).

Three or more failures within three consecutive inspections to meet consumer warning requirements (R.61-106 Sections 2.3.4, 4.2).

Three or more failures within three consecutive inspections to use tanning equipment manufactured in accordance with 21.CFR 1040.20 regarding compliant labeling (recommended lamps and/or recommended exposure schedule missing or not legible) (R.61-106 Section 3.4.1).

Three or more failures within three consecutive inspections to ensure timer accuracy requirements when the timer inaccuracy is greater than 20 percent (R.61-106 Sections 3.4.3, 3.4.9).

Three or more failures within three consecutive inspections to ensure maximum exposure time requirements (R.61-106 Section 3.4.3).

A required system designed to prevent or mitigate a serious safety event is absent or inoperable due to a deliberate act by a registrant such as: removing a timer (R.61-106 Sections 3.4.3, 3.4.5) or device designed to enable the consumer to terminate manually radiation emission (R.61-106 Section 3.4.6); failure to provide compliant physical protective barriers (R.61-106 Section 3.4.8); or, failure to replace defective filters (R.61-106 Section 3.8.3).

Three or more failures within three consecutive inspections to comply with override timer control requirements (R.61-106 Section 3.4.3.1-3.4.3.5).

Three or more failures within three consecutive inspections to adequately indicate timer intervals in such a manner that the exposure time cannot be reasonably set (R.61-106 Section 3.4.4).

Three or more failures within three consecutive inspections to ensure a timer does not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when emission from the tanning device has been terminated (R.61-106 Section 3.4.5).

Three or more failures within three consecutive inspections to ensure a tanning device is provided with an emergency off switch (R.61-106 Section 3.4.6).

Three or more failures within three consecutive inspections to ensure tanning equipment meets the National Fire Protection Association National Electrical Code, is provided with ground fault protection or other means for preventing shock (R.61-106 Section 3.4.7).

Three or more failures within three consecutive inspections to ensure tanning equipment has physical barriers to protect consumers from injury induced by touching or breaking the lamps (R.61-106 Section 3.4.8).

Three or more failures within three consecutive inspections to ensure a tanning device is maintained in good repair in order to prevent any mechanical safety hazards (R.61-106 Section 3.4.11).

Three or more failures within three consecutive inspections to ensure physical barriers protect persons who are not using a tanning device from line-of-sight accidental ultraviolet radiation exposure (R.61-106 Section 3.4.12).

Three or more failures within three consecutive inspections to ensure consumers have compliant protective eyewear (R.61-106 Section 3.6.1).

Failure to prohibit consumers from tanning when a consumer does not have compliant protective eyewear (R.61-106 Section 3.6.2).

Three or more failures within three consecutive inspections to instruct consumers in the proper utilization of protective eyewear prior to initial exposure (R.61-106 Section 3.6.3).

Three or more failures within three consecutive inspections to ensure protective eyewear is used in accordance with manufacturer's design, instructions or approval (R.61-106 Section 3.6.5).

Three or more failures within three consecutive inspections to ensure protective eyewear is in optimal condition (R.61-106 Section 3.6.4).

Three or more failures within three consecutive inspections to ensure protective eyewear meets the requirements of 21 CFR 1040.20 (c)(4) (4-1-87 edition) (R.61-106 Section 3.6.6).

Three or more failures within three consecutive inspections to properly sanitize protective eyewear or tanning equipment (R.61-106 Section 3.7).

Failure to submit a report of actual or alleged injury (R.61-106 Section 4.4).

Two or more failures within three consecutive inspections to use lamps equivalent or compatible under 21 CFR 1040.20 (R.61-106 Section 3.8.1).

Use of lamps for medical use only (R.61-106 Section 3.8.4).

Three or more failures within three consecutive inspections to comply with the manufacturer's recommended maximum exposure time in minutes (R.61-106 Section 5.3.1).

Three or more failures within three consecutive inspections of allowing the operation of the tanning equipment in such a manner so as to cause an injury to a consumer (R.61-106 Section 5.3.3).

Three or more failures within three consecutive inspections to ensure consumers have not tanned less than twenty-four hours between visits (R.61-106 Section 5.3.4).

Three or more failures within three consecutive inspections to ensure that only the consumer using the tanning equipment is in the room or area with the tanning equipment while the tanning equipment is in operation (R.61-106 Section 5.3.6).

#### Moderate

Three or more failures within three consecutive inspections to correct violations within sixty days when the violations have moderate safety significance (R.61-106 Section 1.7.2).

Three or more failures within three consecutive inspections to correct violations involving matters pertaining to failure to follow or establish procedures, rules and regulations that have more than minor safety significance (R.61-106 Section 2.3).

Three or more failures within three consecutive inspections to maintain required records (R.61-106 Sections 2.3, 4.2, 4.3, 4.4, 5.3.2).

Three or more failures within three consecutive inspections to use tanning equipment manufactured in accordance with 21.CFR 1040.20 (R.61-106 Section 3.4.1).

Three or more failures within three consecutive inspections to comply with additional requirements for stand-up booths or any other cabinet or vertical tanning device (R.61-106 Section 3.5).

Three or more incidents within three consecutive inspections of allowing minors to use tanning equipment without proper consent (R.61-106 Section 4.5).

Three or more failures within three consecutive inspections to ensure that the tanning equipment is only operated by adequately trained personnel (R.61-106 Section 5.2).

Three or more failures within three consecutive inspections to train operators as provided by R.61-106 Sections 5.4 (R.61-106 Sections 5.4, 5.5, 5.6, 5.7).

Three or more instances within three consecutive inspections of making, selling, transferring, lending, repairing, assembling, recertifying, upgrading or installing tanning equipment without it meeting all applicable regulations, when placed into operation (R.61-106 Section 6.9.3).

#### Minor

Three or more failures within three consecutive inspections to correct violations involving matters pertaining to failure to follow or establish procedures, rules and regulations that have minor safety significance (R.61-106 Section 2.3).

Repeated violations (three or more failures within three consecutive inspections) not covered in a more severe category that have minor safety significance.

#### 1.13.4.4 Examples of Violations Categorized by Deviation from the Requirement.

#### Major

Failure to allow authorized Department personnel access to tanning facilities and/or equipment to conduct inspections or investigations (R. 61-106 Section 1.4.1).

Failure to allow authorized Department personnel access to records during an inspection or investigation upon reasonable notice (R.61-106 Section 1.4.2).

Three or more failures within three consecutive inspections to correct violations within sixty days (R.61-106 Section 1.7.2).

Continuation of registrant activities after revocation of registration (R.61-106 Section 1.11.4, 1.11.8).

Three or more failures within three consecutive inspections to post inspection results (R.61-106 Section 1.14).

Three or more incidents of making false material statements to the Department (R.61-106 Section 1.15).

Three or more failures of a person to apply for registration prior to beginning operation of a tanning facility (R.61-106 Section 2.2.1).

Three or more failures of a person to supply supporting information to the Department for application review (R.61-106 Sections 2.2.2, 2.2.3).

Three or more failures within three consecutive inspections to follow established operating procedures (R.61-106 Section 2.3.1).

Three or more incidents of operating a tanning facility without prior issuance of a registration approval document or notification from the Department of an approval to operate (R.61-106 Sections 2.4.3, 2.4.4).

Three or more failures of a registrant to register tanning equipment (R.61-106 Section 2.6.1).

Three or more incidents of a tanning facility having its registration denied, suspended or revoked (R.61-106 Section 2.8).

Three or more failures within three consecutive inspections to post warning signs (R.61-106 Section 3.3.1, 3.3.2).

Three or more failures within three consecutive inspections to maintain a record of operator training (R.61-106 Section 5.7).

Three or more incidents of providing tanning vendor services without being registered with the Department (R.61-106 Sections 6.2, 6.4.3).

Three or more incidents of a person failing to provide a complete application for registration of tanning equipment servicing or services (R.61-106 Section 6.3).

Continuation of registrant activities after revocation of registration (R.61-106 Section 6.8).

Three or more failures within three consecutive inspections of a person to notify the Department in writing within thirty days when he has sold, leased, transferred, lent, assembled, recertified, upgraded or installed tanning equipment (R.61-106 Section 6.9.1).

Three or more incidents within three consecutive inspections of failing to meet requirements for formal trainers (R.61-106 Section 6.10.1, 6.10.2, 6.10.5, 6.10.6). Also add as applicable for temporary tanning equipment operator training.

Failure to allow authorized Department personnel to audit any training class (R.61-106 Section 6.10.8).

#### Moderate

Three or more failures within three consecutive inspections by a registrant to notify the Department in writing within twenty days of a violation citation with regards to corrective action taken or planned to correct each violation (R.61-106 Section 1.7.1).

Three or more failures within three consecutive inspections to maintain required records (R.61-106 Sections 1.10, 3.8.2, 4.3.4, 4.6).

Three or more incidents within three consecutive inspections of prohibited advertisement or posting (R.61-106 Section 2.7).

Three or more incidents within three consecutive inspections of utilizing an unregistered provider of tanning equipment servicing or services (R.61-106 Section 2.9).

Three or more failures within three consecutive inspections to perform quarterly tests of timers or emergency off switches (R.61-106 Sections 3.4.9, 3.4.10).

Three or more failures within three consecutive inspections to instruct consumers regarding the selected exposure time (R.61-106 Section 5.3.5).

Three or more incidents within three consecutive inspections of failure to report a change to the Department in writing (R.61-106 Section 6.6).

Three or more incidents within three consecutive inspections of prohibited advertisement (R.61-106 Section 6.7).

Three or more incidents within three consecutive inspections of failure to maintain records of course completion and test results (R.61-106 Section 6.10.3).

Three or more incidents within three consecutive inspections of failure to provide the Department with training course results (R.61-106 Section 6.10.4).

Three or more incidents within three consecutive inspections of failing to notify the Department in writing of any training class being conducted (R.61-106 Section 6.10.7).

#### Minor

Failure by a registrant to notify the Department in writing within twenty days of a violation citation with regards to corrective action taken or planned to correct each violation (R.61-106 Section 1.7.1).

Failure of a registrant to register tanning equipment within thirty days (R.61-106 Section 2.6.1).

Failure of a vendor to notify the Department of installation of tanning equipment by the tenth of each month (R.61-106 Section 6.9.1).

### **1.14 Posting of Inspection Results:**

Each registrant shall post the results of its most recent radiological health inspection.

1.14.1 The inspection results shall be posted in such a manner that the inspection is clearly visible, not obstructed by any barrier, equipment or other object, and can be easily viewed by a consumer prior to entering any tanning device.

1.14.2 The inspection results shall be clearly labeled immediately above the inspection results with the words "DHEC INSPECTION RESULTS" in letters at least one inch tall and a statement "Contact DHEC at (803) 737-7400 if there are any questions" in letters at least one inch tall.

1.14.3 The inspection results shall be posted on forms provided by the Department.

1.14.4 The inspection results shall not be removed until the next Department inspection is performed or unless authorized by the Department in writing.

1.14.5 The registrant may post its response to the Department's inspection and the Department's inspection compliance letter alongside or in close proximity to the inspection results required to be posted by Section 1.14. These cannot be posted over or on top of the inspection results.

### **1.15 Material False statement:**

It shall be a violation to make a material false statement to the Department regarding information contained in the application for registration, information pertaining to an inspection or any other information required by any provision of these regulations.

**1.16 Severability:**

If any provision of this regulation or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the regulation which can be given effect without the invalid provision or application, and to this end the provisions of the regulation are severable.



## **PART II**

### **REGISTRATION OF TANNING FACILITIES AND EQUIPMENT**

#### **2.1 Purpose and Scope:**

This Part provides for the registration of facilities and equipment which employ ultraviolet and other lamps for the purpose of tanning the skin of the human body through the application of ultraviolet radiation.

#### **2.2 Application for Registration of Tanning Facilities:**

2.2.1 Each person acquiring or establishing a tanning facility shall apply for registration of such facility prior to beginning operation of such a facility.

2.2.2 The registrant shall complete and submit all information required by DHEC 0826, Registration of Tanning Equipment. The application shall contain all the information required by such forms and any supporting information as described in Section 2.2.3. The Department shall review the information required to be submitted by DHEC 0826 and shall determine if the information is adequate. The Department shall issue a letter of registration approval if the information required to be submitted by DHEC 0826, this Section and Section 2.3 is found to be adequate and the application fee required by Section 1.11.1 has been paid.

2.2.3 The Department shall require the following supporting information, as a minimum, to be submitted for review and approval with DHEC 0826: 1) the geographic areas of the State to be covered, if the application is for a mobile tanning facility; 2) copies of the consent forms and statements which the consumer, parent or guardian will be required to sign pursuant to Sections 4.2 and 4.5 of this regulation; 3) Copies of the medical and skin history system and copies and/or a description of the exposure record system required to be completed pursuant to Section 4.2; 4) Operating procedures as described in Section 2.3; 5) Copy of each manufacturer's recommended exposure schedule and the recommended lamps for each model of tanning device and a copy of any proposed alternate exposure schedule; 6) a copy of a formal training certificate for each operator or proof of successful completion of a formal training class or approved temporary training; 7) a copy of any other operating and safety procedures unique to facility operation; 8) certification that the applicant has read and understands the requirements of this regulation. Such certification shall be signed and dated by the manager and the owner of the tanning facility.

#### **2.3 Operating Procedures:**

2.3.1 The registrant shall establish and submit operating procedures for Department review and approval. The Department shall review the operating procedures and shall determine if the procedures are adequate. If the procedures are adequate, the Department shall approve the operating procedures, and the registrant shall adhere to the operating procedures in all respects. Any changes to the approved operating procedures shall be submitted to the Department in writing. The registrant must not incorporate the changes into the operating procedures until the Department has approved the changes in writing.

2.3.2 As part of the operating procedures required under this Section, the registrant shall establish and use a procedural manual that will aid in protecting the consumer from excessive or unnecessary exposure to ultraviolet radiation. This procedural manual shall be kept at the registrant's facility and must be available at all times to operators and Department inspectors. Each registrant's procedural manual shall include, at a minimum:

1) instructions to the consumer, to include but not be limited to: illiterate or visually impaired persons unable to sign their name; minors; completion and review of the tanning profile or client card; consumer use of medications; consumers with contact lenses; consumers with cataracts; consumers with skin problems; consumers with current or previous other health conditions; removal of makeup and other substances; nude tanning; pregnant consumers; tanning of children; indoor/outdoor tanning; and, consultation of records;

2) use of protective eyewear;

3) suitability of prospective consumers for tanning equipment use;

4) adherence to the manufacturer's recommended exposure schedule, or an approved alternate exposure schedule as described in Section 2.3.3 of this regulation, or the procedures used for determining to allow a consumer to exceed the schedule as described in Section 2.3.4, including determining exposure times, frequency of visits, spacing of visits and maximum exposure time(s) in minutes;

5) quarterly testing of tanning equipment timers and emergency off switches;

6) handling of complaints of actual or alleged ultraviolet radiation injury from consumers;

7) records to be maintained on each consumer;

8) sanitizing tanning equipment and protective eyewear;

9) use of potentially photosensitizing medications and substances;

10) training requirements;

11) requirements of R.61-106.

2.3.3 Alternate exposure schedule. A registrant may submit for Department consideration and approval an alternate method for determining exposure times and frequencies. Any proposed alternate exposure schedule shall be supported by reliable, accurate and reproducible scientific evidence of results from a reputable source. The source of this supporting information cannot be generated by the registrant. The Department will allow use of an alternate exposure schedule under the following conditions:

2.3.3.1 The alternate exposure schedule and supporting test data and results shall be submitted in writing for Department review and written approval prior to its use;

2.3.3.2 The manufacturer's recommended exposure schedule shall be submitted to the Department along with the proposed alternate exposure schedule;

2.3.3.3 The manufacturer's recommended lamp or a documented equivalent lamp shall be used;

2.3.3.4 The testing laboratory or other testing institution used shall be recognized by the Food and Drug Administration for conducting spectroradiometric measurements and testing;

2.3.3.5 A complete report of calibration shall be submitted to the Department, to include indication that a valid, scientific basis exists and is documented for the alternate exposure schedule.

2.3.3.6 The maximum exposure time for any applicable timer shall not be able to be set to a time greater than the manufacturer's recommended maximum exposure time;

2.3.3.7 The alternate exposure schedule shall meet all criteria outlined by the Food and Drug Administration's Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products issued August 21, 1986; and

2.3.3.8 The alternate exposure schedule shall be posted in the tanning room for which it is to be used and shall be readily available for the operator's use.

2.3.4 The registrant may allow a consumer to exceed the manufacturer's recommended exposure schedule, or an alternate exposure schedule approved under Section 2.3.3 of this regulation, provided that the consumer is educated regarding the potential risks associated with tanning beyond such exposure schedules. Consumer education must include a document signed by the consumer informing the consumer of the potential risks and an oral review of the information contained in the document. The document must be signed on a consumer's initial visit, and must be renewed at least annually thereafter or maintained continually throughout the consumer's patronage of the facility. The document signed by the consumer must include the following language verbatim:

For All Consumers:

#### **DANGER - ULTRAVIOLET RADIATION**

Follow instructions.

Avoid too frequent or lengthy exposure. As with natural sunlight, exposure can cause serious skin injury and allergic reactions. Repeated exposure may cause chronic sun damage characterized by wrinkling, dryness, fragility and bruising of the skin and skin cancer.

**WEAR PROTECTIVE EYEWEAR. FAILURE TO USE PROTECTIVE EYEWEAR IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.**

Ultraviolet radiation from sunlamps will aggravate the effects of the sun. Do not sunbathe before or after exposure to ultraviolet radiation.

Certain foods, medications (including, but not limited to, tranquilizers, diuretics, antibiotics, high blood pressure medication, birth control pills and skin creams), cosmetics or toiletries may increase your sensitivity to the ultraviolet radiation. Consult a physician before using sunlamp or tanning equipment if you are using medications or have a history of skin problems or believe yourself to be especially sensitive to sunlight.

Pregnant women or women who are using birth control pills who use this product may develop discolored skin.

If you do not tan in the sun, you are unlikely to tan from the use of this product.

Prior to consenting to be exposed beyond the recommended exposure schedule. I was given the opportunity to read the warning above and I confirm that:

1. fully recognize the risks of injury or illness inherent in the use of suntanning equipment, to include the risks of exceeding the exposure times, spacing of visits or number of visits per week in accordance with the manufacturer's recommended exposure schedule.
2. I have completed a medical and skin history evaluation.
3. I have been advised regarding potential skin sensitivity from use of certain foods, medications, cosmetics or toiletries.
4. I have been shown how to use FDA-compliant protective eyewear and I agree to wear the protective eyewear during each tanning session.
5. I have been warned to consult a physician if I have a history of skin problems or if I am especially sensitive to sunlight.
6. I have been advised regarding what the manufacturer's recommended exposure schedule states regarding exposure times, spacing of visits, number of visits per week and skin types.
7. I have been advised by a tanning equipment operator that tanning indoors and out in the same day, tanning at multiple salons, or similar occurrences, are hazardous to my health.
8. I have been shown how to use the tanning equipment properly.

I have been advised that tanning is a process, and that immediate skin darkening does not have to be evident for the process to be working. Multiple visits may be necessary before results are beginning to show.

10. I will advise a tanning equipment operator of any change in medications or new use of medications.

11. I will advise a tanning equipment operator of any redness, burn, rash or other injury associated with the use of the tanning equipment.

**USE OF THIS TANNING EQUIPMENT IN EXCESS OF THE MANUFACTURER'S RECOMMENDED EXPOSURE SCHEDULE COULD RESULT IN THE INCREASED RISK OF ADVERSE HEALTH EFFECTS, TO INCLUDE BURNING, SKIN CANCER, PREMATURE SKIN AGING, AND ALLERGIC REACTIONS. THE SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL STRONGLY DISCOURAGES EXCEEDING THE EXPOSURE TIMES IN MINUTES, NUMBER OF VISITS PER WEEK, OR SPACING OF VISITS IN ACCORDANCE WITH THE EXPOSURE SCHEDULE.**

I acknowledge that I have been informed as to the potential risk of exposure beyond the manufacturer's recommended exposure schedule, and hereby consent to such additional exposure.

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Signature of Consumer	Date	Signature of Operator	Date
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For individuals under the age of eighteen (18), parent or legal guardian must also sign consenting to the above warning and for use of tanning equipment.

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Signature of Consumer	Date	Parent or Legal Guardian	Date
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For illiterate or visually impaired persons unable to sign their name:

I have read the warning to \_\_\_\_\_ in the presence of the witness, \_\_\_\_\_, and to the best of knowledge the consumer understands the risk associated with this warning.

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Signature of Consumer	Date	Signature of Operator	Date
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## **2.4 Issuance of Registration Approval Document:**

2.4.1 Upon determination that an application meets the requirements of this regulation and the application and tanning facility fees have been paid, the Department shall issue a registration approval document.

2.4.2 The Department may incorporate in the registration approval document, at the time of issuance or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of tanning equipment and tanning facilities as the Department deems appropriate or necessary.

2.4.3 No person shall operate a tanning facility until the Department has issued a registration approval document or otherwise received notification from the Department of an approval to operate.

2.4.4 Any facility found operating unregistered shall immediately cease operation until approval by the Department is issued.

## **2.5 Transfer of Registration:**

No registration shall be transferred from one person to another or from one tanning facility to another tanning facility.

## **2.6 Report of Change:**

2.6.1 The registrant shall notify the Department in writing within thirty days of making any change which would render the information contained in the application for registration or the registration approval document no longer accurate.

2.6.2 This requirement shall not apply for changes involving replacement of tanning equipment lamps, or changes involving the addition or deletion of tanning equipment operators.

## **2.7 Prohibited Advertisement and Posting:**

2.7.1 No person, in any advertisement or posting, shall refer to the fact that such person or such person's facility is registered with the Department pursuant to the provisions of this regulation, and no person shall state or imply that any activity under such registration has been approved by the Department.

2.7.2 No person, in any advertisement or posting, shall indicate that such person's tanning equipment is safe or free of hazards from ultraviolet radiation. This includes such statements as "no burning," "no harmful rays," "no adverse affects," "safe tanning," "healthy" or similar wording of concepts.

2.7.3 No person, in any advertisement or posting, shall claim any medical or health benefits from such person's tanning equipment, nor imply use as a medical device or treatment.

2.7.4 No person or facility shall advertise or promote tanning packages labeled as "unlimited."

2.7.5 No person, in any advertisement or posting, shall promote tanning exposure times, number of visits per week, or spacing of visits in excess of those in accordance with the manufacturer's recommended exposure schedule or Department approved alternate exposure schedule.

## **2.8 Denial, Suspension or Revocation of Registration:**

2.8.1 The Department may deny an application or suspend or revoke registration or a registration approval document issued pursuant to this regulation: 1) for any material false statement in the application for registration or in the statement of fact required by provisions of this regulation; or 2) for falsification or alteration of records required to be kept by this regulation; or 3) because of conditions revealed by the application or any report, record, inspection or other means which would warrant the Department to refuse to grant a certificate of registration on an original application; or 4) for operation of the tanning facility in a manner that causes or threatens to cause hazard to the public health or safety; or 5) for failure to allow authorized representatives of the Department to enter the tanning facility at reasonable times for the purpose of determining compliance with the provisions of this regulation, conditions of the registration approval document or an order of the Department; or 6) for failure to pay any fee required in Section 1.11 of this regulation; or 7) for failure to correct violations within sixty (60) calendar days from the date of the citation; or 8) for violation of, or failure to observe any of the terms and conditions of the registration approval document, this regulation, or an order of the Department; or 9) when the current owner of the tanning facility has one or more of the following at another salon: outstanding compliance issues, a poor compliance history, outstanding fees or penalties due, unresolved enforcement action, or a Major severity level violation.

2.8.2 Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for suspension or revocation of a registration approval, the Department shall: 1) call to the attention of the registrant, in writing, the facts or conduct which may warrant such actions, and 2) provide reasonable opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.

2.8.3 Any person aggrieved by a decision by the Department to deny a registration approval or to suspend or revoke a registration approval after issuance may request a hearing under provisions of the South Carolina Administrative Procedures Act.

2.8.4 The Department may terminate a registration approval upon receipt of a written request for termination from the registrant.

**2.9 Verification of Service Representative:**

Each registrant shall not engage any person to provide tanning equipment servicing or services as described in this Part until such person provides evidence that he has been registered with the Department as a provider of services in accordance with these regulations.

## PART III

### STANDARDS FOR THE CONSTRUCTION AND OPERATION OF TANNING EQUIPMENT

#### 3.1 Purpose and Scope:

This Part provides for the construction and operation of tanning equipment which employ ultraviolet and other lamps for the purpose of tanning the skin of the human body through the application of ultraviolet radiation.

#### 3.2 Construction and Operation of Tanning Equipment:

Except as otherwise ordered or approved by the Department, each tanning facility shall be constructed, operated and maintained in accordance with the requirements in this regulation.

#### 3.3 Warning Signs:

3.3.1 The following warning sign shall be conspicuously posted in the immediate proximity (within one meter) of each piece of tanning equipment; it shall be readily legible, clearly visible, and not obstructed by any barrier, equipment, or other item present so that the consumer can easily view the warning sign before energizing this tanning equipment.

#### **“DANGER - ULTRAVIOLET RADIATION**

Follow instructions. Avoid too frequent or lengthy exposure. As with natural sunlight, exposure can cause serious skin injury and allergic reactions. Repeated exposure may cause chronic sun damage characterized by wrinkling, dryness, fragility and bruising of the skin and skin cancer.

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**WEAR PROTECTIVE EYEWEAR. FAILURE TO USE PROTECTIVE EYEWEAR IN ACCORDANCE WITH THE MANUFACTURER’S INSTRUCTIONS MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.**

Ultraviolet radiation from sunlamps will aggravate the effects of the sun. Do not sunbathe before or after exposure to ultraviolet radiation. Certain foods, medications (including, but not limited to, tranquilizers, diuretics, antibiotics, high blood pressure medication, birth control pills and skin creams), cosmetics or toiletries may increase your sensitivity to the ultraviolet radiation. Consult a physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. Pregnant women or women who are using birth control pills who use this product may develop discolored skin. If you do not tan in the sun, you are unlikely to tan from the use of this product.”

The lettering on each warning sign shall be at least ten (10) millimeters high for all words shown in capital letters and at least five (5) millimeters high for all lower case letters.

3.3.2 The following warning sign shall be conspicuously posted in the immediate proximity (within one meter) of each piece of tanning equipment; it shall be readily legible, clearly visible, and not obstructed by any barrier, equipment, other item present so that the consumer can easily view the warning sign before energizing this tanning equipment:



If you receive any injury, such as a burn or other physical injury, from the use of this tanning device, you should report this injury immediately to a tanning equipment operator and immediately, within twenty-four (24) hours, to the SC Department of Health and Environmental Control, Radiological Health Branch, 2600 Bull Street, Columbia, SC 29201, or contact the Department by telephone at (803) 737-7400.

The lettering on each warning sign shall be at least one inch high for all words.

### **3.4 Equipment and Facility Construction Requirements:**

3.4.1 The registrant shall use only tanning equipment manufactured in accordance with the specifications set forth in 21 CFR 1040.20, "Sunlamp products and ultraviolet lamps intended for use in sunlamp products." The exact nature of compliance shall be based on the standards in effect at the time of manufacture as shown on the device identification label required by 21 CFR 1010.3.

3.4.2 Each assembly of tanning equipment shall be designed for use by only one consumer at a time.

3.4.3 Each assembly of tanning equipment shall be equipped with a timer which complies with the requirements of 21 CFR 1040.20 (c) (2). The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time. No timer interval shall have an error exceeding plus or minus ten percent of the maximum timer interval for the product.

3.4.3.1 All tanning equipment shall be provided with an override timer control installed outside of the room in which a tanning device is located.

3.4.3.2 The remote timer shall be operated only by a formally trained operator and shall be located so that the consumer cannot easily set or reset the consumer's own exposure time.

3.4.3.3 The remote timer(s) shall comply with the requirements for timers as provided in Section 3.4.

3.4.3.4 New facilities shall install remote timers during the installation of the tanning equipment. Existing facilities with a change of ownership shall not receive an application approval document without proof of the remote timer installation.

3.4.3.5 Existing tanning devices not equipped with a remote timer control system shall have the remote timer(s) installed within a year of the effective date of these regulations.

3.4.4 The timer intervals shall be indicated in such a manner that it is consistent with the exposure times on the manufacturer's recommended exposure schedule or the Department approved alternate exposure schedule.

3.4.5 The timer may not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when emission from the tanning device has been terminated.

3.4.6 Each assembly of tanning equipment shall be provided with a control on the equipment to enable the consumer to terminate manually radiation emission from the equipment at any time without disconnecting the electrical plug or removing any ultraviolet lamp.

3.4.7 Tanning equipment shall meet the National Fire Protection Association National Electrical Code and shall be provided with ground fault protection on the electrical circuit, or other methods for preventing shock.

3.4.8 Tanning equipment shall include physical barriers to protect consumers from injury induced by touching or breaking the lamps.

3.4.9 The registrant shall ensure that tests are performed quarterly on each assembly of tanning equipment and documented in writing to ensure the timer is accurate to within ten percent (10%) as specified in Section 3.4.3 and the consumer is able to terminate the radiation manually as specified in Section 3.4.6. The tests shall include the date of the test and the timer test shall include the indicated time versus the measured time. The timer shall be tested at the tanning equipment manufacturer's recommended maximum exposure time.

3.4.10 Timer and emergency off switch tests shall be performed upon initial installation, prior to the initial use of the timer device by a consumer and also upon any repair or replacement of the timer or emergency off switch. The date of each test shall be recorded and any timer test shall include the indicated time versus the measured time. The timer shall be tested at the tanning equipment manufacturer's recommended maximum exposure time.

3.4.11 The tanning devices shall be maintained in good repair in order to prevent any mechanical safety hazards.

3.4.12 There shall be physical barriers around each tanning device which is in use to protect persons who are not using the device from line-of-sight accidental ultraviolet radiation exposure.

### **3.5 Additional Requirements for Stand-up Booths and Any Cabinet or Vertical Tanning Device:**

3.5.1 Tanning booths designed for stand-up use shall also comply with the following additional requirements:

1) Booths shall have physical barriers or other means compliant with 21 CFR 1040.20, such as floor markings, to indicate the manufacturer's recommended exposure position or minimum use distance between the ultraviolet lamps and the consumer's skin;

2) Booths shall be constructed with sufficient strength and rigidity to withstand the stress of use and the impact of a falling person;

3) Access to booths shall be of rigid construction with doors which are non-locking and open outwardly; and

4) The floor inside each booth shall be kept clean and shall be maintained in a non-slip manner.

### **3.6 Protective Eyewear:**

3.6.1 If a consumer does not provide protective eyewear, the registrant shall have compliant protective eyewear available for each consumer to use during any use of tanning equipment.

3.6.2 If a consumer fails to provide compliant protective eyewear and chooses not to use the protective eyewear available from the registrant, then the consumer shall not be allowed to tan.

3.6.3 Prior to initial exposure, the tanning facility operator shall instruct the consumer in the proper utilization of the protective eyewear required by this regulation, to include use in accordance with the manufacturer's design, instructions and approval.

3.6.4 Tanning facility operators shall ensure all protective eyewear is in optimal condition.

3.6.5 Tanning facility operators shall ensure the protective eyewear to be used by the consumer is to be used in accordance with its design.

3.6.6 The protective eyewear in this regulation shall meet the requirements of 21 CFR 1040.20 (c) (4) (4-1-87 edition).

### **3.7 Sanitation:**

3.7.1 The registrant shall ensure that the protective eyewear provided by the registrant required by this regulation are properly sanitized before each use and shall not rely upon exposure to the ultraviolet radiation produced by the tanning equipment itself to provide sanitizing. The sanitizer used shall be one intended and documented for use on protective eyewear and is registered with the Environmental Protection Agency and the Department. The sanitizer shall be mixed and used according to the manufacturer's instructions.

3.7.2 The registrant shall ensure that a salon employee properly sanitizes the tanning equipment between every use by a consumer. The tanning equipment shall be properly sanitized in order to prevent the spread of pathogens. The sanitizer used shall be one intended and documented for use on tanning equipment which is registered with the Environmental Protection Agency and the Department. The areas of the tanning equipment that shall be sanitized include, but are not limited to, the handrails, headrests and bed surfaces. The sanitizer shall be mixed and used according to the manufacturer's instructions.

3.7.3 A torn or cracked pillow or headrest shall be immediately removed from use until it has been replaced or repaired. Any repair shall be such that the pillow or headrest can be sanitized properly.

3.7.4 A registrant shall not require a consumer to sanitize the tanning equipment or protective eyewear and shall not post any signs requesting such sanitation be performed by the consumer. However, this does not prevent a consumer from resanitizing the tanning equipment or protective eyewear if a consumer so chooses after the registrant has performed the sanitation.

### **3.8 Replacement of Ultraviolet Lamps, Bulbs or Filters:**

3.8.1 The registrant shall only use lamps which have been certified with the Food and Drug Administration (FDA) as "equivalent" lamps under the FDA regulations and policies applicable at the time of the replacement of the lamps. The format for the equivalency document shall be in compliance with 21 CFR 1040.20, and shall be in the form of User Instructions.

3.8.2 The registrant shall maintain manufacturer's literature demonstrating the equivalency of any replacement lamps that are not identified as original equipment. The documents for any lamps currently in use shall be kept at the facility and shall be readily available for Department review.

3.8.3 Defective lamps or filters shall be replaced before further use of the tanning equipment.

3.8.4 Lamps and bulbs designated for medical use only shall not be used.

## **PART IV**

### **RECORDS, REPORTS AND INSTRUCTIONS**

#### **4.1 Purpose and Scope:**

This Part provides for the records and reports to be submitted or maintained by registrants of tanning equipment which employ ultraviolet and other lamps for the purpose of tanning the skin of the human body through the application of ultraviolet radiation.

#### **4.2 Consumer Warning:**

4.2.1 Prior to initial exposure, a tanning facility operator shall require that the consumer sign and date a warning statement that the information in Sections 3.3.1, 4.2.3, 4.2.4, 4.2.5, and 4.2.6 has been read and understood, and a tanning facility operator shall require the consumer to complete a detailed medical and skin history information. An operator shall review the warning statement and medical and skin history information prior to the consumer's initial visit or upon any resubmission of this information. The documents must be signed on a consumer's initial visit, and must be renewed at least annually thereafter or maintained continually throughout the consumer's patronage of the facility.

4.2.2 For illiterate or visually impaired persons, the warnings in Sections 4.2.3, 4.2.4, 4.2.5, and 4.2.6 shall be read by an operator in the presence of a witness and the witness and the operator shall sign a statement that the information has been read and understood.

4.2.3 Each consumer shall be warned by the operator as to the potential photosensitizing agents and the operator shall determine if the consumer is using any of these agents to the best of his or her ability. A list of common photosensitizing agents will be provided to all registrants by the Department. The registrant shall have the list of potential photosensitizing agents readily available for review.

4.2.4 Each consumer shall be warned by the operator to consult a physician if the consumer has a history of skin problems or is especially sensitive to sunlight. Documentation of this warning shall be recorded in writing by the operator on the consumer's skin and medical history information.

4.2.5 Upon their initial visit, consumers shall be advised by a tanning equipment operator that tanning indoors and outdoors in the same day, tanning at multiple salons, or other similar occurrences, are hazardous to their health. Documentation of this warning shall be recorded in writing by the operator on the consumer's skin and medical history information.

4.2.6 Upon their initial visit, each consumer shall be warned by the operator to advise the operator of any use of medications. Documentation of this warning shall be recorded in writing by the operator on the consumer's skin and medical history information.

#### **4.3 Records:**

4.3.1 All records required to be kept in this section and Section 4.2 shall be maintained for at least two years, or longer if required by any other applicable law, regulation, or any other part of this regulation. The records shall be maintained at the facility and shall be readily available for Department review.

4.3.2 The registrant shall maintain a record of all consumer warning statements given to each consumer as required in Section 4.2.

4.3.3 The registrant shall maintain a record of each consumer's total number of tanning visits, dates of each visits, the durations of each tanning exposures, the room number or name for each tanning visit, and the consumer's skin type.

4.3.4 The registrant shall maintain records ensuring that the requirements of Sections 3.4.3 and 3.4.6 have been met.

4.3.5 Records required by these regulations which are maintained by the registrant on computer systems shall be regularly copied, at least monthly, and updated on storage media other than the hard drive of the computer. An electronic record shall be retrievable as a printed copy.

#### **4.4 Report of Injury:**

4.4.1 The registrant shall submit to the Department a written report of actual or alleged injury from use of the registrant's tanning equipment within five working days after notification thereof. The consumer that is injured or allegedly injured must report the injury within seventy-two (72) hours of the occurrence.

4.4.2 The report shall include the following information that has been obtained to the best ability of the registrant: 1) the name, address and telephone number of the affected individual; 2) the name, location, telephone number, name of operator on duty, and registration number of the tanning facility and identification of the specific tanning equipment involved; 3) the nature of the actual or alleged injury, and any other information relevant to the actual or alleged injury to include the date and duration of exposure; 4) name of attending physician, if applicable, medical attention sought and treatment; 5) copy of all of the individual's medical, skin and exposure history; 6) steps taken to prevent recurrence of future injuries; 7) all information required to be provided by DHEC 0827, Report of Injury; and 8) any other information the Department deems is necessary.

4.4.3 Any records pertaining to or any reports of actual or alleged injury shall be maintained by the registrant and shall be available for review until the Department authorizes their disposal.

#### **4.5 Use of Tanning Equipment by Minors:**

The registrant shall not allow minors to use tanning equipment unless the minor provides a consent form and a statement, described in Section 4.2, signed by the minor's parent or legal guardian while witnessed by an operator or the owner of the tanning facility. The witness shall provide his/her name, signature, title and date on the consent form.

#### **4.6 Users' Instruction:**

The users' instructions as required by 21 CFR 1040.20 (e) (1) shall be maintained and available for review for each model of tanning equipment used at the tanning facility. The documents shall be kept at the facility and shall be readily available for Department review.

## **PART V**

### **OPERATOR REQUIREMENTS**

#### **5.1 Purpose and Scope:**

This Part provides for the requirements of the operators of tanning equipment which employ ultraviolet and other lamps for the purpose of tanning the skin of the human body through the application of ultraviolet radiation.

#### **5.2 Operator Presence:**

The registrant shall ensure that the tanning equipment is only operated by an adequately trained operator present at the tanning facility. The adequately trained operator shall meet the requirements of Sections 5.4, -5.5, 5.6, and 5.7.

#### **5.3 Operator Control:**

5.3.1 The registrant shall ensure that no operator allow any consumer to use tanning equipment greater than the manufacturer's recommended maximum exposure time(s) in minutes, or the Department approved alternate maximum exposure time in minutes.

5.3.2 If a consumer is accelerated for any valid reason along the manufacturer's recommended exposure schedule, then a formally trained operator shall determine the point or week at which the customer will begin to tan and document in detail on the consumer's records why the consumer was allowed to begin at a greater exposure time than the minimum exposure time for his or her skin type according to the manufacturer's recommended exposure schedule.

5.3.3 The operator shall ensure the tanning equipment is not operated in such a manner so as to cause an overexposure or injury to the consumer.

5.3.4 If the registrant knows or has reason to know that the consumer had tanned less than twenty four hours previously, then the registrant shall not allow that person to tan.

5.3.5 Prior to each use of a tanning device, each consumer shall be instructed by a trained operator regarding the selected exposure time as determined by the operator.

5.3.6 The operator shall ensure that only the consumer using the tanning equipment shall be in the room or area with the tanning equipment while the tanning equipment is in operation.

#### **5.4 Operator Training:**

The registrant shall certify that all tanning equipment operators as defined by Section 1.2.8 are formally trained and knowledgeable in the correct operation of the tanning equipment used at the facility to adequately inform and assist each consumer in the proper use of the tanning equipment. Each operator shall be trained in at least the following prior to allowing consumers to tan:

- 1) the requirements of these regulations R.61-106, "Tanning Facilities;"
- 2) the tanning facility operating procedures as approved by the Department;

- 3) the Department's Regulatory Guide;
- 4) proper procedures of the use of and the instruction in use of protective eyewear;
- 5) recognition of injury or overexposure to ultraviolet radiation;
- 6) the tanning equipment manufacturer's procedures for operation and maintenance of the tanning equipment;
- 7) all aspects of the tanning equipment manufacturer's recommended exposure schedule or the Department approved alternate exposure schedule including: the determination of skin type of consumers, determination of duration of exposures, frequency of exposures or visits, spacing of sequential exposures or visits, number of visits allowed per week, and maximum exposure time(s) in minutes;
- 8) the classification and determination of skin type of consumers using the skin types outlined in Appendix A of R.61-106;
- 9) knowledge of potential photosensitizing agents, to include food, cosmetics and medications, and the possibility of photosensitivity and photoallergic reactions;
- 10) proper procedures for sanitizing protective eyewear and tanning equipment;
- 11) emergency procedures to be followed in case of an actual or alleged ultraviolet radiation injury;
- 12) biological effects of ultraviolet radiation, to include the potential acute and long term health effects of ultraviolet radiation;
- 13) the human skin and the tanning process;
- 14) testing and record-keeping requirements and maintenance of records required by R.61-106;
- 15) determination of lamp equivalency;
- 16) the requirements of the federal regulations, 21 CFR 1040.20;
- 17) the types and wavelengths of ultraviolet light;
- 18) general information and characteristics of commercial tanning lamps;
- 19) general features of all types of commercial tanning devices; and,
- 20) the public health reasons for avoiding overexposure and the dangers of overexposure.

### **5.5 Facility Specific Operator Training:**

Each registrant shall provide facility specific tanning equipment operator training. Each operator shall be trained and have the training documented prior to allowing a consumer to tan. The registrant shall document the facility specific training on a form provided by the Department or a similar form. The training shall include, but not be limited to:

- 1) the requirements of the regulations, R.61-106, "Tanning Facilities;"
- 2) the registrant's Department approved facility operating procedures;
- 3) procedures for operation of the registrant's tanning equipment;
- 4) all aspects of the manufacturer's recommended exposure schedule(s) or the Department approved alternate schedule(s), to include the items listed by Section 5.4 (7);
- 5) use of the registrant's consumer warning and skin and medical history system as required by Section 4.2;
- 6) use of the registrant's consumer record keeping system as required by Section 4.3;
- 7) proper procedures of the use of and the instruction in use of the registrant's protective eyewear; and
- 8) proper mixing and use of the registrant's tanning equipment and protective eyewear sanitizer, as applicable.

#### **5.6 Formal Operator Training:**

5.6.1 The registrant shall allow operation of tanning equipment only by persons who have successfully completed formal tanning equipment operator training courses approved by the Department.

5.6.2 The formal training courses shall cover the topics in Section 5.4.

5.6.3 The Department reserves the right to require tanning equipment operators to attend another tanning equipment operator formal training class if operator competence cannot be adequately demonstrated to the Department or under any other circumstances the Department deems necessary.

#### **5.7 Temporary Operator Training**

Facility personnel hired as tanning equipment operators shall have a period of thirty (30) days after the effective date of employment to successfully complete the required formal training. Such persons shall work under the direct supervision of a formally trained operator until they have successfully completed the following training. The temporary operator training shall include documented training in all topics outlined in Sections 5.4 and 5.5. The training provided for Section 5.4 may be accomplished through the use of a Department-approved correspondence course.

#### **5.8 Record of Training:**

The registrant shall maintain a record of operator training required in Sections 5.5, 5.6 and 5.7 readily available for inspection by authorized representatives of the Department.



**PART VI**  
**VENDORS**

**6.1 Purpose and Scope:**

This Part provides for the registration of persons providing tanning equipment installation, servicing and/or services and persons providing formal training of tanning equipment operators.

**6.2**

Each person who is engaged in the business of installing or offering to install tanning equipment, or is engaged in the business of furnishing or offering to furnish tanning equipment servicing or services in this State, or provides formal training to tanning equipment operators shall apply for registration of such services with the Department prior to furnishing or offering to furnish any such services. Services may include but shall not be limited to the installation and repair of tanning equipment and associated components, such as bulbs and filters.

**6.3**

Application for registration shall be completed on forms furnished by the Department and shall contain all information required by the Department as indicated on the forms and accompanying instructions.

6.3.1 Each person applying for registration under this Part shall specify:

6.3.1.1 That he has read and understands the requirements of these regulations; and

6.3.1.2 The training and experience that qualify him to provide the services for which he is applying for registration.

6.4 Issuance of Registration Approval Document:

6.4.1 Upon determination that an application meets the requirements of this regulation and the application and tanning equipment vendor fees have been paid, the Department shall issue a registration approval document.

6.4.2 The Department may incorporate in the registration approval document, at the time of issuance or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the vendor's receipt, possession, and transfer of tanning equipment as the Department deems appropriate or necessary.

6.4.3 No person shall provide tanning equipment installation, servicing and/or services until the Department has issued the registration approval document.

**6.5 Transfer of Registration Approval:**

No registration approval shall be transferred from one person to another person or from one tanning equipment vendor to another tanning equipment vendor.

**6.6 Report of Change:**

The vendor shall notify the Department in writing before making any change which would render the information contained in the application for registration or the registration approval document no longer accurate.

#### **6.7 Prohibited Advertisement:**

No person, in any advertisement, shall refer to the fact that such person or such person's business is registered with the Department pursuant to the provisions of this regulation, and no person shall state or imply that any activity under such registration has been approved by the Department.

#### **6.8 Denial, Suspension or Revocation of Registration:**

6.8.1 The Department may deny an application or, suspend or revoke a registration or a registration approval document applied for or issued pursuant to this regulation: 1) for any material false statement in the application for registration or in any statement of fact required by provisions of this regulation; or 2) because of conditions revealed by the application or any report, record, inspection or other means which would warrant the Department to refuse to grant a registration approval on an original application; or 3) failure to install or repair tanning equipment so that it meets the requirements of 21 CFR 1040.20; or 4) for failure to pay the fee required in Section 1.11.3 of this regulation; or 5) for failure to correct violations within sixty (60) calendar days from the date of the citation; or 6) for violation of or failure to observe any of the terms and conditions of the registration approval, this regulation, or an order of the Department.

6.8.2 Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for suspension or revocation of a registration approval, the Department shall: 1) call to the attention of the registrant, in writing, the facts or conduct which may warrant such actions; and 2) provide reasonable opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.

6.8.3 Any person aggrieved by a decision by the Department to deny a registration approval or to suspend or revoke a registration approval after issuance may request a hearing under provisions of the South Carolina Administrative Procedures Act.

6.8.4 The Department may terminate a registration approval upon receipt of a written request for termination from the registrant.

#### **6.9 Vendor Obligation:**

6.9.1 Any person who sells, leases, transfers, lends, assembles, recertifies, upgrades or installs tanning equipment in this State shall notify the Department in writing not later than the tenth day of each month of:

6.9.1.1 The name, address and telephone number of persons who have received this equipment or who have had the equipment recertified or upgraded;

6.9.1.2 The manufacturer, model, and serial number of each piece of tanning equipment transferred, recertified or upgraded; and

6.9.1.3 The date of transfer, recertification or upgrade of each piece of tanning equipment.

6.9.2 Notification to the Department shall be made on DHEC Form 0829.

6.9.3 No person shall make, sell, lease, transfer, lend, repair, assemble, recertify, upgrade or install tanning equipment, lamps or the supplies used in connection with such equipment unless such supplies and equipment when properly placed in operation and used shall meet the requirements of these regulations and the regulations of 21 CFR 1040.20.

#### 6.10 Requirements for Formal Trainers of Tanning Equipment Operators (Training Services):

6.10.1 Vendors of tanning equipment operator training services shall meet the registration requirements of this section. Training services vendors are required to furnish a copy of all training materials, to include a sample examination and answers, to the Department for review and comment along with the application for registration and prior to offering operator training courses. The materials submitted for review shall include, but not be limited to, the credentials of the trainers and persons compiling the training materials, a copy of the classroom curriculum and copies of written materials to be received by the trainees.

6.10.2 Any changes made to the training course shall be submitted in writing to the Department and approved by the Department prior to its use.

6.10.3 Training services vendors shall maintain records of course completion and test results until the Department authorizes their disposal. These records shall be available for Department review upon request.

6.10.4 A list of persons successfully completing the operator training shall be furnished to the Department in writing within thirty days of the training course. The list shall include, but not be limited to: the name of the person(s) conducting the training class, and a list of persons trained with test scores and the tanning facility name and address (if applicable).

6.10.5 Each formal training class shall be conducted in a classroom setting and shall:

1) Be at least six hours in length, excluding items such as registration, lunch, marketing, profit-making strategies, advertising or taking the test;

2) Have a test consisting of at least fifty questions. The passing score shall be correct answers for at least 75% of the questions;

3) Include written material which covers the required subjects, such as training manual; audio-visual presentations which cover the required subjects, such as slides, overheads, or videos; current copies of the Department's regulations, R.61-106; current copies of the Department's Tanning Facility Operating Procedures; current copies of the Department's Regulatory Guide; and a questions and answer period for trainees.

6.10.6 The required subjects shall include, but not be limited to:

6.10.6.1 the requirements of these regulations, R.61-106 "Tanning Facilities;"

6.10.6.2 the Department's Tanning Facility Operating Procedures;

6.10.6.3 the Department's Regulatory Guide;

6.10.6.4 proper procedures for the use and the instruction in use of protective eyewear;

6.10.6.5 recognition of injury or overexposure to ultraviolet radiation;

6.10.6.6 examples of tanning equipment manufacturer's procedures for operation and maintenance of tanning equipment;

6.10.6.7 examples and detailed explanations of tanning equipment manufacturer's recommended exposure schedules;

6.10.6.8 the classification and determination of skin type of consumers using the skin types outlined in Appendix A of R.61-106;

6.10.6.9 potential photosensitizing agents, to include food, cosmetics and medications, and the possibility of photosensitivity and photoallergic reactions;

6.10.6.10 proper procedures for sanitizing protective eyewear and tanning equipment;

6.10.6.11 emergency procedures to be followed in case of an actual or alleged ultraviolet radiation injury;

6.10.6.12 biological effects of ultraviolet radiation, to include the potential acute and long term health effects of ultraviolet radiation;

6.10.6.13 the human skin and the tanning process;

6.10.6.14 testing and record-keeping requirements and maintenance of records required by R.61-106;

6.10.6.15 determination of lamp equivalency and examples of lamp equivalency documents;

6.10.6.16 the requirements of the federal regulations, 21 CFR 1040.20;

6.10.6.17 the types of and wavelengths of ultraviolet light;

6.10.6.18 general information and characteristics of commercial tanning lamps;

6.10.6.19 general features of all types of commercial tanning devices; and,

6.10.6.20 the public health reasons for avoiding overexposure and the dangers of overexposure.

6.10.7 The Department shall receive written notification at least five days prior to a prescheduled training class being conducted and at least twenty-four (24) hours notification prior to a non-prescheduled, in-house (on-site) class being conducted. The notification shall include, but not be limited to: the name of the training vendor; the name of the instructor(s) of the class; the date, time, city location and address location of each class.

6.10.8 The Department shall receive written notification at least five days prior to a training class being cancelled. The notification shall include, but not be limited to: the name of the training vendor; the name of the instructor(s) of the class; the date, time, city location and address location of the class; and, the reason for cancellation of the class.

6.10.9 The Department reserves the right to audit any training class without notice to the training vendor.

## **6.11 Requirements for Trainers of Temporary Tanning Equipment OPERATORS**

6.11.1 Providers of temporary tanning equipment operator training services shall meet the registration requirements of this section. Training services vendors are required to furnish a copy of all training materials, to include a sample examination and answers, to the Department for review and comment along with the application for registration, prior to offering the temporary tanning equipment operator training materials. The materials submitted for review shall include, but not be limited to, the credentials of the persons compiling the training materials, a bibliography of references for the material, and copies of all written materials to be received by the trainees.

6.11.2 Any changes made to the training course shall be submitted in writing to the Department and approved by the Department prior to its use.

6.11.3 Each temporary tanning equipment operator course shall:

6.11.3.1 Have a test consisting of at least fifty questions. The passing score shall be correct answers for at least 75% of the questions;

6.11.3.2 Include written material which covers all of the required subjects outlined in Section 6.10.6;

6.11.3.3 Include a current copy of the Department's regulations. R.61-106; a current copy of the Department's Tanning Facility Operating Procedures; a current copy of the Department's Regulatory Guide; a current copy of DHEC 0827, Report of Injury; a current copy of DHEC 0828. Consumer Statement; and a list of potentially photosensitizing medications and substances.

## **APPENDIX A**

### **SKIN TYPES**

#### **Skin Type I:**

- 1) Burns easily and severely, peels and does not tan.
- 2) Has bright white skin, blue or green eyes, red hair and freckles.
- 3) Indoor and outdoor tanning not recommended.

#### **Skin Type II:**

- 1) Burns easily and severely, peels, tans minimally or lightly.
- 2) Unexposed skin is white, blue or brown eyes, red or blond hair and freckles.

#### **Skin Type III:**

- 1) Burns moderately and tans average.
- 2) Unexposed skin is white, brown eyes, dark hair.

#### **Skin Type IV:**

- 1) Burns minimally, tans easily and above average with each exposure (exhibits IPD-immediate pigment darkening).
- 2) Unexposed skin is light brown, dark eyes, dark hair.

#### **Skin Type V:**

- 1) Rarely burns, tans easily and subsequently, always exhibits IPD.
- 2) Unexposed skin is brown, dark eyes, dark hair.

#### **Skin Type VI:**

- 1) Rarely burns, tans profusely, always exhibits IPD.
- 2) Unexposed skin is black, dark eyes, dark hair.